IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF PENNSYLVANIA

RANDI COHEN AND JAMES COHEN,	)	
	)	
Plaintiffs,	)	2:20-cv-00057
	)	
v.	)	Judge Mark R. Hornak
	)	
JOHNSON & JOHNSON,	)	
	)	
Defendant.	)	
	)	

OPINION

Mark R. Hornak, Chief United States District Judge

Plaintiffs Randi and James Cohen (collectively "Plaintiffs") filed this personal injury, products liability civil action against Defendants' Ethicon Inc. and Johnson & Johnson (collectively "Defendants")[1] alleging a variety of injuries and complications arising from the implantation of Defendants' Gynemesh pelvic mesh device.

On October 31, 2011, Ms. Randi Cohen, a Pennsylvania resident, underwent surgery at a UPMC hospital in Pittsburgh to implant the pelvic mesh in order to treat her pelvic organ prolapse. (ECF No. 28-1, at 5.) After the surgery, Ms. Cohen alleges that she experienced pain and discomfort, resulting in the eventual surgical removal of the pelvic mesh in June of 2013. (*Id.* at 6.) Ms. Cohen alleges that she experienced and continues to experience ongoing discomfort and

[1] The claims were originally brought against Ethicon, Inc. and Ethicon, LLC. (ECF No. 1.) However, after the case was transferred to this Court and the pending Motion was filed, the parties filed a stipulation noting that Ethicon LLC was dismissed in the MDL and that Johnson & Johnson "should be listed as a named defendant." (ECF No. 47.) The Court approved the Stipulation, removed Ethicon LLC as a Defendant, and added Johnson & Johnson as a Defendant on February 5, 2020. (ECF No. 48.) The Court nonetheless refers to "Defendants" in the context of the matters considered here.

pain today as a result of the implantation of the pelvic mesh. (*Id.*; ECF No. 32.) This action was part of the Multi-District Litigation ("MDL") in the United States District Court for the Southern District of West Virginia, *In Re: Ethicon, Inc. Pelvic Repair System Products Liability Litigation*, MDL No. 2327. (*See* ECF No. 38.) This case was transferred to this Court on January 14, 2020 after the completion of discovery under the auspices of the MDL court. (*Id.*; ECF No. 43.)

Plaintiffs' First Amended Master Long Form Complaint brought eighteen (18) claims against Defendants: Negligence (Count I), Strict Liability – Manufacturing Defect (Count II), Strict Liability – Failure to Warn (Count III), Strict Liability – Defective Product (Count IV), Strict Liability – Design Defect (Count V), Common Law Fraud (Count VI), Fraudulent Concealment (Count VII), Constructive Fraud (Count VIII), Negligent Misrepresentation (Count IX), Negligent Infliction of Emotional Distress ("NIED") (Count X), Breach of Express Warranty (Count XI), Breach of Implied Warranty (Count XII), Violation of Consumer Protection Laws (Count XIII), Gross Negligence (XIV), Unjust Enrichment (Count XV), Loss of Consortium (Count XVI), Punitive Damages (Count XVII) and Discovery Rule and Tolling (Count XVIII). (*See* ECF No. 39-1.)

Defendants moved for partial summary judgment on Plaintiffs' claims at Counts I–XVIII. (ECF Nos. 28, 29.) Plaintiffs filed a response in which they conceded that several claims should be dismissed, specifically those at Counts II, XI, XII, XIV, and XV. (ECF Nos. 31, 32.) The Court held a telephonic oral argument on April 16, 2020, at which Plaintiffs then withdrew their claims at Counts IV, XVII and XVIII. (ECF No. 60.) At the oral argument Defendants also indicated that they were not moving for summary judgment as to the claim at Count I, to the extent it rests on a design defect theory, nor as to the loss of consortium claim at Count XVI.

Thus, pending before the Court for decision was Defendants' Motion for Summary Judgment as to Counts I (Negligence – Failure to Warn), III (Strict Liability – Failure to Warn), V (Strict Liability – Design Defect), VI (Common Law Fraud), VII (Fraudulent Concealment), VIII (Constructive Fraud), IX (Negligent Misrepresentation), X (NIED), and XIII (Violation of Consumer Protection Laws). Thereafter, this action was stayed for nine (9) months in light of a proceeding at our Court of Appeals which may have resolved certain claims central to this action. (See ECF Nos. 61–65.) Thereafter, that stay was lifted, and supplemental briefing was authorized and received (ECF Nos 64–67.)

For the reasons explained below, the Court GRANTS in part and DENIES in part Defendants' Motion. Summary judgment is granted in favor of the Defendants and against the Plaintiffs as to the claims at Counts I (failure to warn only), II, IV, VI, VII, VIII, IX, XI, XII, XIII, XIV and XV. The Defendants' Motion for Summary Judgment is denied as to the claims at Counts III, V, and X, and this action will proceed as to those three claims, and as noted below, the claims at Count I (as to the claim for negligence – design defect) and XVI.

I. BACKGROUND

As stated above, Plaintiffs' current action was part of an MDL against Defendants relating to the advertising, design, manufacturing, selling, and use of Defendants' pelvic mesh device. The relevant facts are as follows. On October 31, 2011, Ms. Cohen, in order to treat her pelvic organ prolapse, underwent surgery to implant Defendants' Gynemesh product, a pelvic mesh medical device. (ECF Nos. 29, 32.) The surgery occurred at Magee Womens' Hospital of UPMC in Pittsburgh and was performed by Dr. Halina Zyczynski. (*Id.*) Following the procedure, Ms. Cohen suffered a series of complications and injuries that she alleges were "directly attributable to the

Gynemesh PS." (ECF No. 32, at 2.) Further, Ms. Cohen alleges that Defendants knew about the alleged complications caused by its Gynemesh product and disregarded such when it developed and marketed the product. (*Id.* at 2–3.)

On September 5, 2013, Plaintiffs filed the instant action with Ms. Randi Cohen bringing seventeen (17) claims against Defendants. (ECF No. 1.) Ms. Cohen's husband and co-Plaintiff James Cohen also brought a claim for loss of consortium against Defendants. (*Id.*) The parties agree that Pennsylvania substantive law applies in this case. (ECF Nos. 29, 32); *see also Belanger v. Ethicon, Inc.*, No. 13-12036, 2014 WL 346717, at *7 (S.D.W. Va. Jan. 30, 2014) (holding that cases arising out of the larger MDL should apply the law of "the place where the plaintiff was implanted with the product").

On December 19, 2019, this case was transferred from the MDL to this Court by Order of the MDL Judge, Judge Joseph R. Goodwin. (ECF No. 38.) Judge Goodwin identified this case as "ready to be transferred to the appropriate jurisdiction" because "the time to conduct discovery is complete . . . and the parties have had time to file dispositive and *Daubert* motions, response and replies." (ECF No. 38, at 1.) On January 14, 2020, this case was docketed before this Court and this Court ordered the parties to confer and file a Joint Status Report ("JSR") detailing a plan of suggested action. (ECF No. 44.) The parties provided such on February 5, 2020. (ECF No. 49.) In the JSR, the parties suggested that this Court establish a scheduling order after the present pending Motion for Partial Summary Judgment has been ruled upon by the Court. (*Id.*) After receiving additional papers from the parties, the Court held a telephonic oral argument on the pending Motion. (ECF No. 60.)

At the oral argument, Plaintiffs did not contest Defendants' Motion for Summary Judgment as to the following Counts: (1) Count II (Strict Liability – Manufacturing Defect); (2) Count IV (Strict Liability – Defective Product); (3) Count XI (Breach of Express Warranty); (4) Count XII (Breach of Implied Warranty); (5) Count XIV (Gross Negligence); and (6) Count XV (Unjust Enrichment). (*Id.*) Accordingly, the Court will GRANT summary judgment in favor of the Defendants as to those Counts. In addition, at oral argument the parties agreed that Counts XVII and XVIII (Punitive Damages and Discovery Rule and Tolling) were not cognizable as independent legal claims under Pennsylvania law and the Court dismissed those Counts without prejudice. (*Id.*)

Thus, remaining at issue in Defendants' pending Motion are the following claims: Count I (Negligence – Failure to Warn)[2], Count III (Strict Liability – Failure to Warn), Count V (Strict Liability – Defective Design), Count VI (Common Law Fraud), Count VII (Fraudulent Concealment), Count VIII (Constructive Fraud), Count IX (Negligent Misrepresentation), Count X (Negligent Infliction of Emotional Distress), and Count XIII (Violation of Consumer Protection Laws).

On March 29, 2021, the Court stayed this action pending final disposition of another similar case arising from the Eastern District of Pennsylvania, *Ebert v. C. R. Bard, Inc.*, 459 F. Supp. 3d 637 (E.D. Pa. 2020), which, on appeal, was poised to address the question of whether the Pennsylvania Supreme Court would extend comment k to section 402A of the Restatement

[2] At oral argument, Defendants confirmed that they are not moving to dismiss Plaintiffs' negligent design defect claims.

(Second) Torts to cases involving medical devices,[3] a central issue, *inter alia*, in this action. (ECF No. 61.) However, on November 10, 2021, apparently due to a settlement, the Third Circuit granted the appellant's unopposed motion to dismiss the appeal in *Ebert*, and as a result, discontinued its certification to the Pennsylvania Supreme Court. (ECF No. 64.) Accordingly, and after receiving a Joint Status Report from the parties requesting that this Court lift the stay and rule on the pending Motion, this Court lifted the stay in this case and ordered additional briefing from the parties on any updated and applicable case law relating to the pending Motion. (ECF No. 65.) The parties then provided such briefing. (*See* ECF Nos. 66, 67.)

The matter is now ripe for disposition.

II. LEGAL STANDARD

Under Federal Rule of Civil Procedure 56, summary judgment is proper "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). On summary judgment, it is not the court's role to weigh the disputed evidence and decide which is more probative, or to make credibility determinations. *Boyle v. Cnty. of Allegheny*, 139 F.3d 386, 393 (3d Cir. 1998). Instead, the court must consider the evidence and all reasonable inferences which may be drawn from it in the light most favorable to the non-moving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986) (citing *United States v. Diebold, Inc.*, 369 U.S. 654, 655 (1962)). If a conflict arises between the evidence presented by the parties, the court must accept as true the allegations

[3] In that case, the Third Circuit had requested that the Supreme Court of Pennsylvania accept by certification the questions at issue in *Ebert*, which involved open questions of Pennsylvania tort law, including whether comment k was applicable to medical devices. (*See Ebert v. C. R. Bard, Inc.*, Appeal No. 20-2139, Doc No. 50.) As a result, this Court further continued the stay in this case. (ECF No. 62.)

of the non-moving party, and "all justifiable inferences are to be drawn in his favor." *Anderson v. Liberty Lobby*, 477 U.S. 242, 255 (1986).

When a party with the burden of proof fails to produce sufficient evidence to prove their claim, summary judgment may be granted. *Saldana v. K-Mart Corp.*, 260 F.3d 228, 232 (3d Cir. 2001). And when the non-moving party bears the burden of proof on an issue, it may not merely rely on the allegations in its pleadings to survive summary judgment but must set forth sufficient facts showing that there is a genuine issue for trial. *Id.*

III. DISCUSSION

Count I of the Amended Complaint alleges that Defendants were negligent in the "manufacturing, design, warning, instruction, training, selling, marketing, and distribution" of its Gynemesh product. (ECF No. 39-1, at 24–26.) Count III alleges that Defendants "failed to properly and adequately warn and instruct the Plaintiffs and their health care providers" about the safest and most effective methods of implantation and the risks and benefits of the products. (*Id.* at 28–30.) Count V alleges that Defendants' Gynemesh product was "not reasonably safe for its intended use and was defective" in design. (*Id.* at 31–32.) Counts VI–VIII allege that Defendants made false and/or fraudulent representations about the product to the medical and health community that the Gynemesh product was tested and found to be safe and effective. (*Id.* at 33–44.) Plaintiffs allege that Defendants either fraudulently concealed and intentionally or recklessly omitted pertinent information about risks associated with the Gynemesh product from their representations to healthcare providers and to Plaintiffs and breached their duty to disclose to Plaintiffs and to physicians the alleged defective nature of the product. (*Id.*)

Counts IX–X allege that Defendants were negligent in making allegedly false representations to the medical community and to Plaintiffs by failing to exercise ordinary care in making representations with respect to the "manufacture, sale, testing quality assurance, quality control, and distribution" of the Gynemesh product. (*Id.* at 44–46.) Finally, Count XIII alleges that Plaintiffs bought and used the Gynemesh product for personal use and suffered "ascertainable losses" as a result of Defendants' violation of the state consumer protection laws. (*Id.* at 50–54.) Plaintiffs further allege that but for the Defendants "deceptive conduct," they would not have purchased the Gynemesh product, and that Defendants deceptive and fraudulent representations made in "marketing and promotional materials" violated the consumer protection laws of Pennsylvania. (*Id.*)

Defendants' Motion seeks summary judgment on all of these Counts. (ECF Nos. 28, 29.) The Court will address each in turn.

A. Strict Liability Claims

First, Defendants argue that Plaintiffs' remaining strict liability claims at Count III (Failure to Warn) and Count V (Defective Design) are barred under Pennsylvania law because "Pennsylvania courts, applying comment k of the Restatement (Second) of Torts § 402A, do not recognize strict liability claims in cases involving prescription drugs and medical devices." (ECF No. 29, at 4.) Conversely, Plaintiffs argue that "the Pennsylvania Supreme Court has not extended or applied comment k of § 402A to bar strict liability claims against medical device manufacturers and Defendants cite no Pennsylvania Supreme Court cases which apply comment k to immunize medical device manufacturers from strict liability design defect claims." (ECF No. 32, at 5.)

The Court concludes that these strict liability claims are cognizable under Pennsylvania law and in this case, so Defendants are not entitled to summary judgment on Plaintiffs' strict liability claims. Accordingly, the Summary Judgment Motion as to Counts III and V is DENIED.

Here's why.

i. Applicability of comment k

The central dispute between the parties is whether Pennsylvania strict liability law has extended comment k of the Restatement (Second) of Torts § 402A, which precludes the application of strict liability to certain products, to cover prescription medical devices. In *Hahn v. Richter*, 673 A.2d 888, 889–90 (Pa. 1996), the Pennsylvania Supreme Court adopted comment k in the context of prescription drugs and concluded that strict liability could not be applied to prescription drugs where adequate warnings of the drugs' potential risks had been provided.

Although the Pennsylvania Supreme Court has not extended comment k to cover medical devices, following *Hahn*, several courts (including the Pennsylvania Superior Court) have categorically barred strict liability claims from proceeding as to prescription medical devices, in reliance on comment k.[4] *See e.g.*, *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006) ("We find no reason why [*Hahn*'s rationale] may not be applied to medical devices."); *see also Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 466 (E.D. Pa. 2015) (collecting cases finding that plaintiffs may not assert strict liability claims against device manufacturers); *Mills v. Ethicon, Inc.*, 406 F. Supp. 3d 363, 378 (D.N.J. 2019) ("Federal courts, faced with the same issue

[4] Since the Pennsylvania Supreme Court has not spoken on this issue, this Court must predict how the Pennsylvania Supreme Court would decide it. *See Berrier v. Simplicity Mfg., Inc.*, 563 F.3d 38, 45–46 (3d Cir. 2009) ("In the absence of a controlling decision by the Pennsylvania Supreme Court, a federal court applying that state's substantive law must predict how Pennsylvania's highest court would decide [the] case.")

of Pennsylvania law, have unanimously held that comment k applies to medical devices, barring strict liability design defect and failure-to-warn claims"); *Kohn v. Ethicon, Inc.*, No. 19-40004, 2020 WL 733126 (E.D. Pa. Feb. 13, 2020) (agreeing that this area of Pennsylvania law is unsettled and predicting that the Pennsylvania Supreme Court would find that strict liability claims against medical device manufacturers are not cognizable); *Atkinson v. Ethicon, Inc.*, No. 13-697, 2019 WL 3037304, at *5 (W.D. Pa. July 11, 2019) ("As to strict liability, there is a split among federal district courts applying Pennsylvania law as to whether strict liability is an available cause of action against the manufacturer of a medical device; yet, even under the most permissive interpretation, such claims exist only with respect to manufacturing defects in medical devices and not with respect to other theories of strict liability."); *Eneida Lopez v. Ethicon*, No. CV 20-2694, 2020 WL 5569770, at *5 (E.D. Pa. Sept. 17, 2020) ("[T]his Court predicts that the Supreme Court of Pennsylvania would apply its holding in *Hahn* to medical devices . . ."); *McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 537 (E.D. Pa. 2021) ("[T]his Court predicts that the Pennsylvania Supreme Court would extend its reasoning in *Hahn* to preclude strict liability manufacturing defect claims against medical device manufacturers."); *Mikula v. C.R. Bard, Inc.*, No. 2:21-CV-01307-MJH, 2021 WL 5989130 (W.D. Pa. Dec. 17, 2021).

However, primarily relying on two post-*Hahn* cases, other courts have declined to categorically exclude strict liability claims involving prescription medical devices. *See, e.g.*, *Patchcoski v. W.L. Gore & Assocs., Inc.*, No. CV 3:19-1556, 2020 WL 4335016, at *10 (M.D. Pa. July 28, 2020) (predicting that the Pennsylvania Supreme Court would not extend *Hahn* and comment k to all prescription medical device manufacturers); *Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448 (W.D. Pa. 2019*), motion to certify appeal denied*, No. 3:17-

CV-220, 2019 WL 7499923, at *8–10 (W.D. Pa. Dec. 19, 2019) (predicting that the Pennsylvania Supreme Court would hold that strict liability claims against medical device manufacturers are cognizable); *Moultrie v. Coloplast*, No. 18-231, 2020 WL 1249354 (W.D. Pa. Mar. 16, 2020) (determining that "extending comment k to medical devices is a matter that should be addressed by the Pennsylvania General Assembly or the Pennsylvania Supreme Court" and allowing the strict liability claims to proceed).

Courts that have declined to extend comment k to medical devices mostly rely on the Pennsylvania Supreme Court decisions in *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014) and *Lance v. Wyeth*, 624 Pa. 231, 261 n.21 (2014). *See Schrecengost v. Coloplast Corp.*, 425 F. Supp. 3d 448, 463–66 (W.D. Pa. 2019); *Ebert v. C.R. Bard, Inc.*, 459 F. Supp. 3d 637, 651–52 (E.D. Pa. 2020). For the reasons explained below, this Court is similarly persuaded that *Tincher* and *Lance* are "persuasive and an indication of how [the Pennsylvania Supreme Court] would rule on this issue." *Schrecengost*, 425 F. Supp. 3d at 463.

In *Tincher*, the Pennsylvania Supreme Court expressed skepticism of wholesale bars on the availability of the strict liability doctrine in products liability cases. The *Tincher* court reiterated that "[n]o product is expressly exempt and, as a result, the presumption is that strict liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." *Tincher*, 628 Pa. at 386. While the court cited *Hahn* as standing for the premise that a manufacturer is immune from strict liability defective design claims, "upon sale of prescription drugs without adequate warning," and did not specifically overrule or limit that principle, *Tincher's* general caution against making categorical exemptions for strict liability indicates to this Court that the

Pennsylvania Supreme Court would be skeptical of extending *Hahn's* holding to medical devices as a categorical matter.[5]

Further, in *Lance*, the Pennsylvania Supreme Court expressed skepticism about *Hahn's* reach in a footnote, stating that "it is our perspective that [the *Hahn* court] applied a rather one-dimensional analysis in its adoption of a blanket approach to comment k in the first instance. For example, the terse opinion in *Hahn* does not mention, let alone evaluate, the reasons why many other jurisdictions had interpreted comment k to require a case-by-case assessment concerning the availability of its protections. *Compare, e.g., Hahn*, 543 Pa. at 560–63, 673 A.2d at 889–91, *with Toner*, 732 P.2d at 304–09. We emphasize that we are not revisiting *Hahn*; rather, our point is only that the truncated analysis in the *Hahn* line offers a poor foundation for extrapolation." 624 Pa. 231, 261, 85 A.3d 434, 452 n.21 (2014). In this Court's estimation, this assessment by the Pennsylvania Supreme Court significantly undermines the strength and persuasive value of the analysis and applicability of *Hahn*, though it does not explicitly overrule *Hahn's* ultimate holding as to prescription drugs.

Reading *Lance* and *Tincher* together, this Court is persuaded that comment k likely would not be applied by the Pennsylvania Supreme Court to categorically bar the applicability of strict liability principles as to all medical devices. And even if the Pennsylvania Supreme Court were to extend comment k to cover medical devices in some fashion, this Court concludes that it would not do so using the same more modest analysis utilized by the same court in *Hahn* and by the

[5] *See Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 390, 104 A.3d 328, 384 (2014) ("Our decision is limited to the context of a 'design defect' claim by the facts of this matter, albeit the foundational principles upon which we touch may ultimately have broader implications by analogy.")

Pennsylvania Superior Court in *Creazzo*.[6] Instead this Court concludes that the Pennsylvania Supreme Court likely would conclude that strict liability claims are cognizable against medical device manufacturers, and that the extension of comment k to bar strict liability claims may only apply as to certain medical devices and only when as evaluated on a case-by-case basis and only after consideration of the full and developed factual record. *Ebert*, 459 F. Supp. 3d at 652–53.

Based on a review of the record here, the Court determines that it does not establish that comment k should be extended to the Gynemesh product in this case. Comment k of the Restatement (Second) of Torts § 402A excludes "unavoidably unsafe products" from strict liability claims. These products are described as "some products which, in the present state of human

[6] Some other courts, including some within this District, place greater weight on *Creazzo* upon determining that in the "absence of controlling Third Circuit or Pennsylvania Supreme Court precedent," courts are to "give serious consideration to the decisions of the intermediate appellate courts in ascertaining and applying state law." *Mikula v. C.R. Bard, Inc.*, No. 2:21-CV-01307-MJH, 2021 WL 5989130, at *5 (W.D. Pa. Dec. 17, 2021) (citing *Robinson v. Jiffy Executive Limousine Co.*, 4 F.3d 237, 242 (3d Cir. 1993)). However, this Court concludes, as have other courts, that *Creazzo* is less than persuasive and should be given less consideration in predicting the direction that the Pennsylvania Supreme Court would take on this issue. *See Schrecengost.* 425 F. Supp. 3d at 465.

First, *Creazzo* was not based on a comprehensive review of policy considerations in deciding that comment k should be extended to medical devices. Rather the Superior Court simply stated that because it found "no reason why the same rationale [in *Hahn*] applicable to prescription drugs may not be applied to medical devices," the lower court made no reversible error in applying comment k to the medical device at issue in that case. *Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. 2006). Second, the Pennsylvania Supreme Court has not cited, endorsed or adopted the holding in *Creazzo* with respect to medical devices and strict liability. Thus, there is reason to doubt the persuasive value of *Creazzo* and when considered in conjunction with *Lance* and *Tincher*, these observations as to the reasoning and treatment (or lack thereof) of *Creazzo* is "other persuasive data" that the Pennsylvania Supreme Court would decide this issue of the applicability of comment k to medical devices differently than did the court in *Creazzo*. *See West v. Am. Tel. & Tel. Co.*, 311 U.S. 223, 237 (1940) ("Where an intermediate appellate state court rests its considered judgment upon the rule of law which it announces, that is a datum for ascertaining state law which is not to be disregarded by a federal court *unless it is convinced by other persuasive data that the highest court of the state would decide otherwise*.") (emphasis added); *see also, Taransky v. Sec'y of U.S. Dep't of Health & Hum. Servs.*, 760 F.3d 307, 316 (3d Cir. 2014) ("[W]e may consider the decisions of state intermediate appellate courts, which, '[a]lthough not dispositive, ... should be accorded significant weight *in the absence of an indication that the highest state court would rule otherwise*.'" (emphasis added) (internal citations omitted).

knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts, § 402A cmt. k.

Such products are considered not to be unreasonably dangerous or defective even when they have an unavoidable, high degree of risk because the protection they provide is so beneficial that use of the product is "fully justified." *Id.* (using the example of the rabies vaccine which often causes "serious and damaging consequences" when injected, however, is considered not unreasonably dangerous because it protects against a disease that "invariably leads to a dreadful death"). Such products are "especially common in the field of drugs . . . and vaccine[s]" however, the comment states that other products "which . . . cannot legally be sold except to physicians, or under the prescription of a physician" or that are "new and experimental . . . [such that], because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients" may fall within the purview of the comment. *Id.*

Manufacturers of such "unavoidably unsafe products" are "not to be held to strict liability for unfortunate consequences attending their use, merely because [the manufacturer] has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk." *Id.*

The record before the Court does not demonstrate that the Gynemesh product should be classified as such an "unavoidably unsafe product." The product is not generally implanted to prevent a life-threatening condition, and the record does not reveal that such was the purpose of its implantation for Ms. Cohen. (ECF No. 32, at 6.) Nor is there any evidence that it is incapable of being made safe for its intended use. (*Id.*) To the contrary, Plaintiffs have presented expert reports which demonstrate that the product could have been more safely designed. (*Id.*) Further,

though Gynemesh is a prescription-only medical device, the Court declines to categorically bar the application of strict liability to claims arising from its use simply because the medical device requires a prescription, absent any other showing that the product carries an "unavoidable high degree of risk" but is "new or experimental" and "apparently useful and desirable" such that the risk is justifiable. *See Schrecengost*, 425 F. Supp. 3d at 465–66 (declining to categorically bar strict liability claims against a prescription-only surgical mesh product and deferring to the "general rule in Pennsylvania that no product is immune from strict liability."). Thus, based on the record here, the Court concludes that the strict liability claims in this case are cognizable as related to the medical device at issue.

Accordingly, the Court must next examine whether Plaintiffs' strict liability claims are sufficiently supported so as to survive summary judgment. The Court determines that Defendants are not entitled to summary judgment on Plaintiffs' strict liability claims because there are genuine issues of material fact that would prevent the entry of judgment as a matter of law in favor of the Defendants.

ii. Strict Liability, on the Merits

Under Pennsylvania law, manufacturers may be held strictly liable for "any product in a defective condition unreasonably dangerous to the user or consumer" if "(a) the seller is engaged in the business of selling such a product, and (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold." *Webb v. Zern*, 422 Pa. 424, 427 (1966) (citing and adopting the Restatement (Second) of Torts 402A). The manufacturer will be held liable for injury even if "the seller has exercised all possible care" in preparing the product and even if "the user or consumer has not bought the product from or entered into any

contractual relation with the seller." *Id.* In other words, strict liability, unlike negligence, is "product-oriented," not "conduct-oriented." *Harford Mut. Ins. Co. v. Moorhead*, 396 Pa. Super. 234, 251 (1990). And, "[t]here are three different types of defective conditions that can give rise to a strict liability claim: design defect, manufacturing defect, and failure-to-warn defect." *Phillips v. A-Best Prod. Co.*, 542 Pa. 124, 131, 665 A.2d 1167, 1170 (1995).

Here, Plaintiffs allege strict liability only under the design defect and failure to warn theories. The Court will address each in turn.

iii. Strict Liability, Design Defect

Under § 402A, adopted as Pennsylvania law, to make out a strict liability claim "a plaintiff must establish that the product was defective, that the defect was a proximate cause of the plaintiff's injuries, and that the defect causing the injury existed at the time the product left the seller's hands." *Davis v. Berwind Corp.*, 547 Pa. 260, 267 (1997). With respect to causation, a plaintiff must prove that the defective product "was a substantial factor in causing the injury." *Spino v. John S. Tilley Ladder Co.*, 548 Pa. 286, 293 (1997). Under a design defect theory, a plaintiff "may prove defective condition by showing either that (1) the danger is unknowable and unacceptable to the average or ordinary consumer, or that (2) a reasonable person would conclude that the probability and seriousness of harm caused by the product outweigh the burden or costs of taking precautions." *Tincher v. Omega Flex, Inc.*, 628 Pa. 296, 309 (2014).

Plaintiffs have demonstrated that there is a genuine issue of material fact as to whether there was a defect in the product and whether the defect was the proximate cause of Ms. Cohen's injuries. Plaintiffs produced expert reports from Drs. Veronikis, Guelcher and Karlovsky which state that there were safer, alternative designs for the product, that the design used and marketed

was defective, and that the risks of such products as designed were not disclosed to customers and physicians. (ECF Nos. 31, 32.) Further, Plaintiffs have advanced an expert witness who will testify that the defects in the design were the direct cause of Ms. Cohen's injuries. (*Id.*) There is enough admissible evidence presented in the current record to conclude, taking all reasonable inferences in favor of Plaintiffs, that there is an issue of fact as to whether there was a defect in the product and whether such a defect was a substantial factor in causing Ms. Cohen's injuries.

Accordingly, the Court DENIES Defendants Motion for summary judgment of Plaintiffs claim at Count V and that claim will proceed.

iv. Strict Liability, Failure to Warn

Under a failure to warn theory, a "dangerous product can be considered 'defective' for strict liability purposes if it is distributed without sufficient warnings to notify the ultimate user of the dangers inherent in the product." *Davis*, 547 Pa. 260 at 267. A plaintiff must also still demonstrate that the product was defective and that the defect, and failure to warn about the defect, was the proximate cause of the plaintiff's injuries. *Id.* Further, the "determination of whether a warning is adequate and whether a product is 'defective' due to inadequate warnings are questions of law." *Id.* However "where fact questions exist ... the question of adequacy is one for the jury." *Rowland v. Novartis Pharms. Corp.*, 34 F. Supp. 3d 556, 572 (W.D. Pa. 2014) (citing *In re Avandia Mktg., Sales Practices and Prods. Liab. Litig.*, 817 F. Supp. 2d 535, 545–46 (E.D. Pa. 2011)). Typically, in cases regarding prescription drugs, the adequacy of warnings requires medical expert testimony and as a result the question of adequacy is "ordinarily a question for the jury." *Id.*

Here, the Court determines that there is a genuine issue of material fact as to whether the product was defective, and whether the warnings were adequate. Plaintiffs have presented expert

testimony that can establish that the warnings at the time of Ms. Cohen's surgery did not properly warn of all the known risks associated with the Gynemesh product such that there remain factual issues as to whether the warnings were adequate. Plaintiffs also present expert testimony that supports the conclusion that the warnings were inadequate and were the proximate cause of Ms. Cohen's injuries, *i.e.*, the inadequate warnings were a substantial factor in causing her injuries. *See Schrecengost*, 425 F. Supp. 3d at 462–63, 467 (providing that under negligent failure to warn claims proximate cause requires showing that had the defendant issued a proper warning, that warning would have altered the physician's treatment, but under strict liability failure to warn claims proximate cause only requires a showing that the lack of warnings was "a substantial factor" in bringing about plaintiffs injuries); *see also id.*, (allowing the strict liability failure to warn claims to proceed because Plaintiffs could "show that had [plaintiff] known about these additional risks, she would not have agreed to the surgery").[7]

Accordingly, the Court determines that Defendants are not entitled to summary judgment on Plaintiffs' strict liability failure to warn claim and the Motion is DENIED as to Count III.

[7] Defendants also argue that Plaintiffs' strict liability "failure to warn" claim should be dismissed because Plaintiffs have not shown that different warnings would have altered Ms. Cohen's physician's decision to implant the Gynemesh device, the same argument they make in support of their request for summary judgment on Plaintiffs' negligent failure to warn claim. (ECF No. 29, at 11.) While the Court notes that there is no evidence in the record demonstrating that either Ms. Cohen or her implanting physician would have changed the decision to proceed with the implantation surgery if other, adequate warnings had been given, *see* Section III.D.i, *infra*, the Court also notes that such a showing is not required under the strict liability failure to warn proximate cause standard. Instead, expert testimony may be sufficient to survive summary judgment. *See Moultrie*, No. 18-231, 2020 WL 1249354 at *10 (W.D. Pa. Mar. 16, 2020) (allowing the strict liability failure to warn claims to proceed because Plaintiffs offered expert opinions where the expert "opine[d] that the [the product] is the cause of certain injuries and damages sustained by Plaintiffs.").

B. Learned Intermediary Doctrine

Next, Defendants argue that Plaintiffs' claims at (1) Common Law Fraud (Count VI); (2) Fraudulent Concealment (Count VII); (3) Constructive Fraud (Count VIII); (4) Negligent Misrepresentation (Count IX); and (5) Violation of Consumer Protection Laws (Count XIII) are all barred by the learned intermediary doctrine. For the reasons stated below, the Court agrees and therefore, summary judgment on these claims is GRANTED.

i. Violation of Consumer Protection Laws (Count XIII)

Defendants argue that Plaintiffs cannot prevail under the Pennsylvania Unfair Trade Practices and Consumer Protection Law ("UTPCPL") because it requires proof that Plaintiffs justifiably relied on the Defendants' alleged misrepresentation or deceptive conduct and that such justifiable reliance caused an ascertainable loss. (ECF No. 29, at 7.) Defendants argue that under the learned intermediary doctrine, Defendants were only required to warn the physician, not the patient – in this case Ms. Cohen – so Plaintiffs are unable to prove reliance or causation under the UTPCPL. (*Id.* at 7–8.)

In response, Plaintiffs argue that the learned intermediary doctrine does not bar their UTPCPL claim because Defendants failed to provide and actively concealed essential information relating to the risks associated with Gynemesh from the implanting physicians. (ECF No. 32, at 19.) Accordingly, Plaintiffs argue, Dr. Zyczynski, Ms. Cohen's implanting physician, could not have been sufficiently "learned" because such information was "not disclosed by Ethicon to physicians." ((*Id.*) (citing *Lance v. Wyeth*, 85 A.3d 434, 457 (2014)); *see also Lance*, 85 A.3d at 457 ("[I]n a situation in which no warning would be sufficient, the learned intermediary doctrine

should not apply to diminish the duties of pharmaceutical companies, or to insulate them from liability for a lack of due care.").

The Pennsylvania UTPCPL, 73 Pa. Stat. Ann. §§ 201–1 *et seq.*, *inter alia*, allows plaintiffs to bring a private cause of action for "unfair or deceptive acts or practices" that cause a person to suffer an "ascertainable loss" of money or property. However, "[t]o bring a private cause of action under the [UTPCPL], a plaintiff must show that he justifiably relied on the defendant's wrongful conduct or representation and that he suffered harm as a result of that reliance." *Yocca v. Pittsburgh Steelers Sports, Inc.*, 578 Pa. 425, 438 (2004). Thus, under the UTPCPL the plaintiff must demonstrate that *she* relied on the wrongful representation.

Under the learned intermediary doctrine, adopted in Pennsylvania law, prescription medical device manufacturers have a duty to warn only the implanting physician about the potential and possible dangers associated with the medical device. *Incollingo v. Ewing*, 444 Pa. 263, 282 A.2d 206, 220 (1971), *abrogated on other grounds by Kaczkowski v. Bolubasz*, 491 Pa. 561, 421 A.2d 1027 (1980). There is no duty to warn the recipient of the prescription medical device, and instead the learned intermediary doctrine places the duty to warn the patient on the prescribing physician, not the manufacturer. *In re Avandia Marketing, Sales Practices & Prods. Liab. Litig.*, 624 F. Supp. 2d 396, 420 (E.D. Pa. 2013). As a result, since there is no duty to warn the direct consumer of medical devices under the learned intermediary doctrine, courts have concluded that the consumer patient does not have a cause of action against the manufacturer under the UTPCPL in these cases. *See e.g., Kee v. Zimmer, Inc.*, 871 F. Supp. 2d 405, 411 (E.D. Pa. 2012) ("Under Pennsylvania law, a consumer does not have a cause of action under the UTPCPL against the manufacturer of prescription drugs because prescription drug manufacturers do not

have a duty to disclose information directly to consumers"); *McLaughlin v. Bayer Corp.*, 172 F. Supp. 3d 804, 831 (E.D. Pa. 2016) (applying *Kee* to manufacturers of prescription medical devices); *see also*, *Zafarana v. Pfizer, Inc.*, 724 F. Supp. 2d 545, 558 (E.D. Pa. 2010) ("Plaintiffs' claims depend on a chain of reliance from Defendants to the prescribing physicians and the prescribing physicians to patients. This, however, cannot be used to allow Plaintiffs to claim that they justifiably relied on any representation made by Defendants.")

In *Lance v. Wyeth*, the Pennsylvania Supreme Court suggested that "some of the underpinnings of the [learned intermediary doctrine] principle have come into question in light of changed practices in the prescription drug industry." 624 Pa. 231, 270 (2014). While the Pennsylvania Supreme Court in *Lance* determined that the "learned intermediary doctrine should not apply to diminish the duties of pharmaceutical companies, or to insulate them from liability for a lack of due care" when "no warning would be sufficient," the *Lance* court specifically stated that it "need not consider the wisdom of modifications or exceptions to the doctrine." *Id.* Thus, the *Lance* court did not explicitly or implicitly overrule prior Pennsylvania precedent applying the learned intermediary doctrine to medical device manufacturers. And courts post-*Lance* have continued to apply the learned intermediary doctrine to bar recovery under the UTPCPL.[8] *See e.g.*, *McLaughlin*, 172 F. Supp. 3d at 831 ("Plaintiffs argue that we should not apply the learned intermediary doctrine here because they have alleged that Bayer withheld information from the physicians and, thus, they have functionally alleged the physicians were not actually 'learned.' However, whether or not the

[8] The Court also notes that the *Lance* court did not mention the UTPCPL, nor did it suggest that its skepticism in assessing the learned intermediary doctrine does or should have any impact on prior cases that have barred recovery under the UTPCPL under the doctrine.

physicians were appropriately 'learned' does not affect our conclusion that Plaintiffs cannot prevail on their UTPCPL claim against Bayer because, as patients, they were required to rely on the advice and counsel of their doctors"); *Crockett v. Luitpold Pharm., Inc.*, No. 19-276, 2020 WL 433367, at *9 (E.D. Pa. Jan. 28, 2020) ("A plaintiff cannot satisfy the UTPCPL's 'justifiable reliance' requirement when the defendant does not sell the drug directly to the patient and does not have a duty to warn the patient."); *Brown v. C.R. Bard, Inc.*, No. 5:21-CV-01552, 2022 WL 420914, at *7 (E.D. Pa. Feb. 11, 2022) ("Initially, the Court finds that the learned intermediary doctrine precludes a claim under the UTPCPL [against the manufacturer of a prescription medical device].")

Based on the case law detailed above, the Court determines that Plaintiffs' UTPCPL claim is barred by the learned intermediary doctrine and the claim must be dismissed. Though the Pennsylvania Supreme Court has expressed doubt about the applicability of the learned intermediary doctrine particularly in cases where even an adequate warning to the learned intermediary would not sufficiently protect the ultimate consumer, adoption of the doctrine with respect to the UTPCPL has not been abrogated and here, Plaintiffs have not and cannot establish that Ms. Cohen justifiably relied on any information provided by Defendants since there was no duty for Defendants to provide such information to Ms. Cohen.

Accordingly, Defendants are entitled to summary judgment on Count XIII.

ii. Fraud and Misrepresentation (Counts VI-IX)

Defendants also move to dismiss all of Plaintiffs' fraud and misrepresentation claims at Counts VI–IX as barred by the learned intermediary doctrine. (ECF No. 29, at 7.) Defendants argue that "[j]ustifiable reliance is an essential element of a fraud or misrepresentation claim" and

therefore, the learned intermediary doctrine breaks the chain in establishing reliance. (ECF No. 29, at 8.) Defendants argue that under "Pennsylvania law, a plaintiff cannot assert reliance on a manufacturer's representations when, consistent with the learned intermediary doctrine, all of the representations run from the manufacturer to the prescribing physician." (*Id.*)

In response, Plaintiffs argue that Defendants "cannot claim that the learned intermediary doctrine bars plaintiffs' fraud and misrepresentation claims when it was because of Ethicon's deceptive acts and affirmative misrepresentations in IFUs [Instructions for Use] that Ms. Cohen could not have been provided any warning or information regarding the frequency and severity of [the] risks" (ECF No. 32, at 18–19.) For example, Plaintiffs cite an expert report from Dr. Veronikis demonstrating that "numerous Ethicon corporate documents contradict[ed]" the IFUs for Gynemesh which stated that the mesh material "remains soft and pliable" including one internal memo which acknowledged that the Gynemesh material was "too stiff for use in vaginal tissues." (*Id.* at 18.)

Under Pennsylvania law, to establish a common law intentional misrepresentation claim a plaintiff must show that there was "(1) a representation; (2) which is material to the transaction at hand; (3) made falsely, with knowledge of its falsity or recklessness as to whether it is true or false; (4) with the intent of misleading another into relying on it; (5) justifiable reliance on the misrepresentation; and, (6) the resulting injury was proximately caused by the reliance." *Bortz v. Noon*, 556 Pa. 489, 499 (1999). Additionally, the "tort of intentional non-disclosure has the same elements as intentional misrepresentation, except in the case of intentional non-disclosure, the party intentionally conceals a material fact rather than making an affirmative misrepresentation." *Id.* (internal citations and quotations omitted). "Common law fraud and negligent

misrepresentation are sister claims under Pennsylvania law as the only difference between them is the mental state the plaintiff must prove to succeed." *Blue Cross Blue Shield Ass'n v. GlaxoSmithKline LLC*, 417 F. Supp. 3d 531, 563 (E.D. Pa. 2019). Finally, in order to establish a claim of constructive fraud, a plaintiff must demonstrate a "false statement (or omission) on which the other party acts to his injury, without the element of dishonest intent." *Bucci v. Wachovia Bank, N.A.*, 591 F. Supp. 2d 773, 784 (E.D. Pa. 2008). Further, a plaintiff must establish that there was a "relationship between the parties that would trigger a [Defendant's] duty." *Id.*

Despite the fact that a plaintiff must show justifiable reliance by the plaintiff in order to establish fraud and misrepresentation claims in Pennsylvania, in the context of products liability cases like the present action, courts have determined that the learned intermediary doctrine does not automatically bar all fraud claims. Instead, courts have allowed claims for fraud and misrepresentation to proceed when a plaintiff can demonstrate that the defendant made fraudulent misrepresentations or concealed information from her implanting physician. *See e.g.*, *Mikula v. C.R. Bard, Inc.*, No. 2:21-CV-01307-MJH, 2021 WL 5989130, at *9 (W.D. Pa. Dec. 17, 2021) ("[T]he learned intermediary doctrine does not, in and of itself, preclude [plaintiff's] negligent misrepresentation claim. Instead, [Plaintiff's] negligent misrepresentation claim, based upon [Defendant's] alleged failure to adequately warn his prescribing physician, may be sufficient if said claim satisfies the pleading requirements"); *Keen v. C.R. Bard, Inc.*, 480 F. Supp. 3d 624, 642 (E.D. Pa. 2020) (allowing a negligent misrepresentation claim to survive summary judgment because reliance by the doctor is sufficient to create a material dispute of fact and it is a factual question as to whether the doctor relied on the manufacturer "to expressly disclose more accurate, detailed information" about the product).

Accordingly, the Court determines that the learned intermediary doctrine does not wholesale bar Plaintiffs' fraud and misrepresentation claims at Counts VI–IX. Instead, the Court must examine the merits of the claims.

C. Fraud and Misrepresentation, on the Merits

Defendants argue that if the Court determines that the learned intermediary doctrine does not bar Plaintiffs' claims of fraud and misrepresentation, they are still entitled to summary judgment on these claims because there is no evidence in the record that Ms. Cohen read or relied on these allegedly fraudulent statements. (ECF No. 29, at 9.)

Defendants state that Ms. Cohen specifically averred that she did not receive any written or verbal information from the company about the product before her surgery and there is no other evidence in the record establishing or suggesting that Ms. Cohen read or relied on any company literature before making her decision to permit the implantation of the Gynemesh device. (*Id.*) In response, Plaintiffs argue that Defendants "concealed information and provided misinformation about risks and warnings to Ms. Cohen through her implanting physician, Dr. Zyczinski, who's counsel plaintiff relied upon." (ECF No. 32, at 17.) In other words, according to Plaintiffs, Ms. Cohen ultimately relied on these misrepresentations because her implanting physician relied on these misrepresentations. And Plaintiffs further argue that their expert reports establish the "date, time and place of the alleged fraud," which creates a genuine dispute regarding a material issue of fact as to whether there was fraud and misrepresentation which must be decided by a fact finder. (*Id.* at 17–19.)

As explained above, a plaintiff can make out a claim of fraud and misrepresentation without demonstrating justifiable reliance by the plaintiff specifically, if she can demonstrate that her physician relied on the fraudulent statements. However, there must be concrete evidence and specific facts in the record to establish at least that a genuine issue exists as to whether the physician actually heard and relied on the supposedly fraudulent information and whether or not she relayed that false information to the plaintiff patient, beyond merely alleging such in pleadings. *See Saldana*, 260 F.3d at 232.

Here, the Court determines that Defendants are entitled to summary judgment because no trier of fact could find that either Ms. Cohen or her physician relied on the alleged fraudulent statements and/or misrepresentations of Defendants. First, as the Court noted above, Plaintiffs cannot demonstrate that Ms. Cohen herself justifiably relied on the allegedly fraudulent or misleading statements of Defendants because the Defendants only have a duty to provide information to the learned intermediary, in this case, Dr. Zyczinski, Ms. Cohen's implanting physician. *See Mikula*, 2021 WL 5989130, at *9. However, the record is also devoid of any evidence that Dr. Zyczinski herself received, read, or relied on any materials, written or oral, from Defendants before she made her decision to perform the surgery.

Even taking all reasonable inferences in favor of Plaintiffs, the Court determines that there is inadequate evidence in the record to create a genuine issue of material fact as to what Dr. Zyczinski knew or didn't know, or as to how any alleged statements or (mis)representations from Defendants did or did not affect her decision to surgically implant the Gynemesh product. Further, even if Plaintiffs' experts can establish that the alleged fraud occurred at a certain time, place and date and that the Defendants knew about and failed to disclose internal documents that

demonstrated "discrepancies between [the] risks and complications known to the Defendant," that evidence cannot generate an issue of fact with respect to the necessary element of reliance by Dr. Zyczinski. (ECF No. 32, at 17.) The record does not demonstrate that Dr. Zyczinski personally did or did not review and rely on these warnings in making her decision to proceed with Ms. Cohen's surgery aside from raising a speculative inference that because the proffered expert testimony establishes that the fraud occurred around the time Ms. Cohen underwent her surgery and Defendants "failed to communicate such to *any* implanting surgeons," Ms. Cohen's implanting doctor therefore likely looked at and relied upon the allegedly fraudulent statements as well. (ECF No. 32, at 18.) (emphasis in the original). Even accepting this as true, this type of inference is not one that is reasonable and instead is speculative, and therefore is not sufficient to survive summary judgement.[9]

[9] The Court also notes, and Defendants argue in the alternative, that Plaintiffs negligent misrepresentation claim also fails because it is duplicative of and subsumed by Plaintiffs' negligent failure to warn claim. *See e.g., McGrain v. C.R. Bard, Inc.*, 551 F. Supp. 3d 529, 546 (E.D. Pa. 2021) ("These allegations [of fraudulent misrepresentation] plainly do not take Plaintiff's fraud claims beyond the scope of failure to warn of the alleged risks of Defendants' product. Plaintiff's argument that 'Defendants actively concealed material facts related to the defective nature of the IVC filter, and the dangers associated with it ... [and] misled Plaintiff and Plaintiff's physician to believe that Defendants' IVC filter was safe and effective for PE and DVT' is similarly unavailing. This Court agrees with Defendants that Plaintiff's misrepresentation claims are 'exactly the type of dressed-up failure to warn claims' that other courts have rejected. *Runner*, 108 F. Supp. 3d at 268. Plaintiff's fraud-based claims at Counts VI and IX are, therefore, dismissed with prejudice.").

The Court notes that even if there was enough evidence in the record to establish a genuine issue of fact with respect to Plaintiffs' fraud and negligent misrepresentation, they would be dismissible as subsumed by Plaintiffs' negligent failure to warn claim since they ultimately rely on the same underlying allegations. *See e.g., Goodling v. Johnson & Johnson*, No. 4:21-CV-00082, 2022 WL 414285, at *8 (M.D. Pa. Feb. 10, 2022) ("In the Amended Complaint, [Plaintiffs] make no effort to differentiate their failure to warn and negligent misrepresentation claims, repeating (oftentimes verbatim) the same allegations for both counts. Because the [Plaintiffs] negligent misrepresentation claim 'sound[s] in failure-to-warn' and the 'sole avenue for recovery for these types of claims is negligent failure to warn,' the Court dismisses this claim (Count IX) with prejudice."); *Kline v. Pfizer, Inc.*, No. 08-3238, 2009 WL 32477 (E.D. Pa. Jan. 6, 2009) ("Nonetheless, a review of the fraud allegations set forth in [Plaintiff's] Complaint reveals that these claims are rooted in a theory of failure to warn. . . . While Kline attempts to characterize these claims as 'so much more than a failure to warn claim,' these claims do, in fact, assert liability against [Defendant] for failure to warn. The very basis of these claims is that [Defendant] knew of the dangers associated with [the prescription drug] but fraudulently concealed this knowledge and fraudulently misrepresented that the drug was safe by failing to warn of its dangers. Thus, the very crux of these claims rests on a failure to warn theory of liability.")

As a result, Defendants are entitled to summary judgment on these claims. The Court GRANTS Defendants Motion as to Counts VI–IX.

D. Negligence Claims

Defendants also move for summary judgment on two of Plaintiffs' negligence claims: Count I (Failure to Warn) and Count X (Negligent Infliction of Emotional Distress). With respect to Plaintiffs' negligent failure to warn claim, Defendants argue they are entitled to summary judgment on the merits. Defendants also argue that Plaintiffs' negligent infliction of emotional distress claim should be dismissed as duplicative of and subsumed by their negligent failure to warn claims. The Court will address each such argument in turn.

i. Failure to Warn Negligence Claim

Defendants argue that they are entitled to summary judgment on Plaintiffs' negligent failure to warn claim at Count I because Plaintiffs have not and cannot meet their burden in establishing that Ms. Cohen's implanting surgeon would have altered her decision to proceed with the surgery, if different warnings had been given by Defendants, particularly because Plaintiffs, did not depose Dr. Zyczinski. (ECF No. 29, at 10.) Plaintiffs argue that it is "not necessary to produce direct testimony from a prescribing physician when the consequences of using a drug are known to the manufacturer and are so severe that it can be presumed that the selection of the drug should not be made." (ECF No. 32, at 15.)

Under Pennsylvania law, a plaintiff may recover for a defendant's failure to provide adequate instructions and warnings about the product under a negligence theory. "In order to state a claim for negligent failure to warn under Pennsylvania law, a plaintiff must show that (1) the

defendant manufacturer owed a duty to the plaintiff; (2) the manufacturer breached that duty; and (3) that breach was the proximate cause of the plaintiff's injuries." *Rowland v. Novartis Pharms. Corp.*, 34 F. Supp. 3d 556, 569 (W.D. Pa. 2014). Plaintiffs "must show that [the Defendant] failed to exercise reasonable care in warning of the dangers of its prescription medical device." *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737, 751 (E.D. Pa. 2007). And in cases involving prescription medical devices, "whether a warning was adequate depends on whether [the prescribing physician as the learned intermediary] having considered the 'the data supplied to him by the manufacturer, other medical literature, and any other source available to him, and weighing that knowledge against the personal medical history of his patient,' would use his independent judgment to prescribe a medical device." *Id.* (internal quotations and citations omitted).

Further, the Third Circuit has indicated that "summary judgment is properly granted on a failure to warn claim where the record is devoid of evidence to support the argument that a different warning would have altered [the physician's] prescribing methods." *In re Avandia Mktg., Sales Practices & Prods. Liab. Litig.*, 639 F. A'ppx 874, 878 (3d Cir. 2016). And courts applying Pennsylvania law have consistently held that in failure to warn cases, to establish causation, a party must demonstrate that a different warning could have made a difference to the specific prescribing physician in the specific case. *See e.g.*, *Pavlik v. Lane Ltd./Tobacco Exporters Int'l*, 135 F.3d 876, 882–83 (3d Cir. 1998) ("Our precedents in this area of the law teach that, in a failure to warn case, we focus our causation analysis on the additional precautions that *might* have been taken by the end user had the allegedly defective warning been different. . . . This analysis requires the fact finder at trial or a court on summary judgment to 'consider not only what *did* occur, but also what *might* have occurred. . . . Such a determination as to what *might* have happened necessarily

requires a weighing of probabilities'") (citing the Pennsylvania Supreme Court); *Lineberger v. Wyeth*, 2006 PA Super 35, ¶ 24, 894 A.2d 141, 151 (2006) (finding that summary judgment was appropriate where Appellant's actual doctor, in deposition testimony, stated that he would have prescribed the drug even if the warnings had been different because "Appellant presented no evidence that a different warning would have changed [the physician's] decision to prescribe [the drug] for Appellant"); *Cochran v. Wyeth, Inc.*, 2010 PA Super 131, ¶ 14, 3 A.3d 673, 676–77 (2010) ("Assuming that a plaintiff has established both duty and a failure to warn, a plaintiff 'must further establish proximate causation by showing that had defendant issued a proper warning to the learned intermediary, he would have altered his behavior and the injury would have been avoided.' *Demmler v. SmithKline Beecham Corp.*, 448 Pa. Super. 425, 671 A.2d 1151, 1155 (1996) (citation omitted)."); *see also, Rowland*, 34 F. Supp. 3d at 571 ("There is no basis for the Court to conclude that Pennsylvania law, in its current state, extends a manufacturer's duty to warn beyond the doctor who prescribed the drug to the plaintiff. The Court will therefore analyze the adequacy of the Zometa warnings in the context of *Plaintiffs' prescribing physicians only*.") (emphasis added).

Here, there is no genuine issue of material fact as to whether Defendants alleged failure to warn proximately caused Ms. Cohen's injuries because there is no evidence in the record demonstrating that any different warnings would have impacted Dr. Zyczinski's decision to use the Gynemesh product. In other words, no reasonable inference can be drawn from the record that an adequate warning in this instance would have prevented the injury. Though Plaintiffs argue that no direct testimony on this point is required, the case law, and learned intermediary doctrine as

applied under Pennsylvania law, contradict this assertion.[10] *See e.g., Rosci v. AcroMed, Inc.*, 447 Pa. Super. 403, 669 A.2d 959, 968–69 (1995) ("Thus, the information supplied by the drug manufacturer is only one source a physician must consult, and he is expected to make an independent medical judgment in determining whether a given drug is appropriate for a particular patient. Under the learned intermediary doctrine, as it is applied in Pennsylvania, a manufacturer will be held liable only where it fails to exercise reasonable care to inform the one for whose use the product is supplied of the facts which make the product likely to be dangerous. The intended 'user' in a case involving a prescription drug or device is, of course, the prescribing physician"); *Demmler v. SmithKline Beecham Corp.*, 448 Pa. Super. 425, 434 (1996) ("[T]o create a jury question, the evidence introduced must be of sufficient weight to establish . . . some reasonable likelihood that an adequate warning would have prevented the plaintiff from receiving the drug . . . Absent proof that a more thorough or more explicit warning would have prevented [Plaintiff's] use of [the drug], appellants cannot establish that [Defendant's] alleged failure to warn was the proximate cause of [Plaintiff's] injuries"); *cf., Moultrie v. Coloplast*, No. 18-231, 2020 WL 1249354 at *12 (W.D. Pa. Mar. 16, 2020) (denying summary judgment where the plaintiff submitted expert testimony that the warning was inadequate in addition to testimony from the

[10] Plaintiffs state it is "well-established under Pennsylvania law that it is not necessary to produce direct testimony from a prescribing physician when the consequences of using a drug are known to the manufacturer and are so severe that it can be presumed that the selection of the drug should not be made." (ECF No. 32, at 15.) However, Plaintiffs fail to identify or cite to any Pennsylvania law to back up this assertion. And the Court has found none. Plaintiffs do cite *State ex rel. Johnson & Johnson Corp. v. Karl*, 647 S.E.2d 899, 913–14 (W.Va. 2007), a case from the West Virginia Supreme Court of Appeals that declined to adopt the learned intermediary doctrine to bar a failure to warn claim. However, this case does not apply Pennsylvania law and, the Court notes, it has since been superseded by a statute in West Virginia that specifically adopts the learned intermediary doctrine as a defense to claims of inadequate warning or instructions for medical devices. *See J.C. by & through Michelle C. v. Pfizer, Inc.*, 240 W. Va. 571, 575 n.9 (2018) ("In 2016, the Legislature enacted West Virginia Code § 55-7-30, which provides, in part, that it is the 'intention of the Legislature in enacting this section to adopt and allow the development of a learned intermediary doctrine as a defense in cases based upon claims of inadequate warning or instruction for prescription drugs or medical devices.'")

prescribing doctor that he "was bothered by the general warnings," "was not warned" that the harm suffered by plaintiff could result, and that he would have presented the information to plaintiff if he had known it at the time).

Here, absent facts establishing that Dr. Zyczinski, as the prescribing and implanting physician, would have changed her ultimate decision to prescribe and implant the Gynemesh product in this case if she had been given different warnings, summary judgment for Defendants is appropriate because no trier of fact can properly find proximate causation in this case. While the expert testimony presented in this case may establish a genuine issue of fact as to the adequacy of the warnings, it does not establish a genuine issue of fact as to whether the allegedly inadequate warnings were the proximate cause of Ms. Cohen's injuries without evidence from her physician that had they been different, the outcome (*i.e.*, the decision to proceed with the surgery) might well have been different, also.

Accordingly, the Court GRANTS Defendants' Motion with respect to Count I, Negligent Failure to Warn.

ii. Negligent Infliction of Emotional Distress

Defendants argue that Plaintiffs' remaining negligence-based claim for negligent infliction of emotional distress ("NIED") at Count X fails because it is duplicative of, and subsumed by, Plaintiffs' failure to warn claims at Count I. (ECF No. 29, at 13.) Defendants argue that the "gravamen of Plaintiffs' negligence allegations" is that Defendants were "aware of certain dangers associated with [the Gynemesh product] but failed to convey that information to implanting physicians while at the same time misrepresenting the products' safety." (*Id.*) Defendants argue that 1) this argument, that Defendants provided inaccurate or incomplete information about the

risks associated with the pelvic mesh to physicians, is essentially the same argument made in support of Plaintiffs' NIED claim, 2) Plaintiffs cannot recover under multiple claims for the same failure to warn theory, and 3) therefore, the Court should summarily reject this claim.

Plaintiffs argue that each of their negligence claims are separate and distinct and should be evaluated independently. (ECF No. 32, at 20.) Plaintiffs further argue that Ms. Cohen's NIED claim is "derivative of all of her negligence claims" and it is not "subsumed" solely by her negligent failure to warn claim. (*Id.*) Therefore, Plaintiffs argue, the Court should not dismiss the claim as duplicative and instead the claim should survive summary judgment because there is enough evidence in the record to create a genuine issue of fact as to whether Defendants were negligent and negligently inflicted emotional distress on Plaintiffs.

Under Pennsylvania law, a negligent infliction of emotional distress claim is cognizable in four scenarios: "(1) the defendant had a contractual or fiduciary duty toward the plaintiff; (2) the plaintiff was subjected to a physical impact; (3) the plaintiff was in a zone of danger and reasonably feared impending physical injury; or (4) the plaintiff observed a tortious injury to a close relative. *Runner v. C.R. Bard*, 108 F. Supp. 3d 261, 272 (E.D. Pa. 2015). "A plaintiff must also establish the elements of a negligence claim, i.e., that the defendant owed a duty of care to the plaintiff, the defendant breached that duty, the breach resulted in injury to the plaintiff, and the plaintiff suffered an actual loss or damage." *Wilder v. United States*, 230 F. Supp. 2d 648, 654 (E.D. Pa. 2002) And "negligen[t] infliction of emotional distress is a distinct cause of action cognizable under Pennsylvania law." *Goodling v. Johnson & Johnson*, No. 4:21-CV-00082, 2022 WL 414285, at *9 (M.D. Pa. Feb. 10, 2022) (internal quotations omitted).

In support of their NIED claim, Plaintiffs' Amended Complaint alleges that Defendants "carelessly and negligently manufactured, designed, developed, tested, labeled, marketed and sold the Defendants' Pelvic Mesh Products to Plaintiffs, carelessly and negligently concealing the harmful effects of the Defendants' Pelvic Mesh Products from Plaintiffs, and carelessly and negligently misrepresented the quality, safety and efficacy of the products." (ECF No. 39-1, at 45.) They further allege that Defendants' negligence directly impacted Plaintiffs "in that Plaintiffs have sustained and will continue to sustain emotional distress, severe physical injuries and/or death, economic loses, and other damages" as a result of their decision to purchase the Gynemesh. (*Id.* at 46.)[11] Lastly, Plaintiffs claim that Defendants' conduct was the direct and proximate cause of Plaintiffs injuries. (*Id.*)

Thus, Plaintiffs' claim appears to rest primarily on allegations that Defendants were negligent in designing and providing adequate and proper warnings regarding the Gynemesh product. Plaintiffs also concede that the NIED claim is "derivative" of all of their other negligence claims, including the ones as to which the Defendants did not move for summary judgment, namely, their negligent design defect claim at Count I. *See Maldonado v. Walmart Store No. 2141*, No. CIV.A. 08-3458, 2011 WL 1790840, at *16 (E.D. Pa. May 10, 2011) ("In order to maintain a claim for negligent infliction of emotional distress, there must be an underlying tort.").

Here, the Court determines that there is undisputedly a genuine issue of material fact as to whether Defendants were negligent in designing the Gynemesh product and whether such

[11] Plaintiffs allege "severe and permanent pain, suffering, disability, impairment, loss of enjoyment of life, loss of care, comfort, and consortium, economic loss and damages including, but not limited to medical expenses, lost income, other damages, and/or death" under their general negligence claims at Count I and do not allege "emotional distress" under that theory. (ECF No. 39-1, at 26.) Accordingly, contrary to Defendants' assertion, the allegations do not in actuality "simply recast Plaintiffs' failure to warn claim." (ECF No. 29, at 14.)

negligence caused Ms. Cohen's injuries.[12] There is enough evidence in the record, taking all reasonable inferences in favor of the Plaintiffs, from which a trier of fact could find that Ms. Cohen suffered a physical impact and emotional distress as a result of Defendants alleged negligent behavior. For example, there is evidence in the record that Ms. Cohen suffered emotional distress such as "situational depression/anxiety" and that she has seen a therapist resulting from such from approximately 2011 to the present. (ECF No. 28-1.) Thus, the Court determines that there are genuine issues of fact as to whether there was infliction of emotional harm in this case and that since Plaintiffs' claim is not duplicative of or subsumed by Ms. Cohen's other negligence claims, and that it alleges emotional distress separate from these claims, the Court will DENY Defendants' Motion with respect to the NIED claim.

IV. CONCLUSION

For the reasons set forth above, Defendant's Motion for Partial Summary Judgment at ECF No. 28 is GRANTED in part and DENIED in part. The Court GRANTS Defendants' Motion to the extent it seeks summary judgment in Defendants' favor as to Plaintiffs' claims at Counts I (Negligence – Failure to Warn), II (Strict Liability – Manufacturing Defect), IV (Strict Liability – Defective Product), VI (Common Law Fraud), VII (Fraudulent Concealment), VIII (Constructive Fraud), IX (Negligent Misrepresentation), XI (Breach of Express Warranty), XII (Breach of Implied Warranty), XIII (Violation of Consumer Protection Laws), XIV (Gross Negligence) and, XV (Unjust Enrichment).

[12] Defendants do not move for summary judgment on Plaintiffs claim for negligence under a design defect theory.

The Court DENIES Defendants' Motion to the extent it seeks dismissal of Plaintiffs' claims at Counts III (Strict Liability – Failure to Warn), V (Strict Liability – Design Defect), and X (Negligent Infliction of Emotional Distress). Accordingly, these claims may proceed along with Plaintiffs' claims at Counts I (Negligence – Design Defect) and XVI (Loss of Consortium).

An appropriate Order will issue.

/s/ Mark R. Hornak
Mark R. Hornak
Chief United States District Judge

Dated: October 5, 2022
cc: All counsel of record